REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated November 28, 2006 are respectfully requested. A separate petition for a 3-month extension of time accompanies this amendment.

I. Claim Amendments

Claim 1 has been amended to replace the phrase "coupled to" with "fused in-frame with" and the phrase "treatment of" with "specifically killing". The support for the amendments can be found, for example, Paragraphs 12 and 161. Claims 3 and 5 have been canceled and claims 13, 15, 16, 24, and 26 have been amended. Claims 47-54 are newly added and support therefor can be found in paragraphs 60, 62 and 121.

II. Claim Objections

Claims 1-3, 24 and 26 are objected to as being drawn, in part, to non-elected inventions. Applicants have cancelled claim 3 and amended claims 24 and 26 to include only the elected species. Accordingly, the amendments have made the objections moot.

III. Double Patenting

Claims 1, 2 and 18 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of copending Application No. 10/077,624.

A statutory type (35 U.S.C 101) double patenting rejection can be overcome by cancelling or amending the conflicting claims so they are no longer coextensive in scope. Applicants have amended claim 1 and therefore overcome the statutory type double patenting rejection.

Claim 5 is provisionally rejected for nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of co-pending Application No.

10/077,624. Claim 5 has been canceled; however, the amended claim 26 corresponds to the canceled claim 5.

Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly-owned patent.....when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by the patent" (MPEP section 804; *Eli Lilly & Co. v. Barr Labs., Inc.* 58 USPQ2d 1869 (Fed. Cir. 2001)).

The present application is a continuation-in-part of application No. 10/007,624, filed on Feb. 14, 2002, which is a continuation-in-part of application No. 09/910,358, filed on July 19, 2001, which is a continuation-in-part of application No. 09/378,577, filed on Aug. 20, 1999. Since both the present application and the '624 application stem from the same prior application filed on Aug. 20, 1999, issuance of the present application as a patent would not unjustly extend the term of exclusion since such a patent would have the same expiration date as any patent which would issue from the '624 application.

Accordingly, Applicants respectfully request that the nonstatutory obviousness-type double patenting rejections be reconsidered and withdrawn.

IV. Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3, 10-11, 14-20, and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

To the extent the rejections may be applied to the amended claims, Applicants respectfully traverse.

The factors to be considered in determining whether a disclosure satisfies the enablement requirement include, but are not limited to, A) the breath of the claims; B) the nature of the invention; C) the state of the prior art; D) the level of one of

ordinary skill; E) the level of predictability in the art; F) the amount of direction provided by the inventor; G) the existence of working examples; and H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

A) The breath of the claims. The amended claim 1 is directed to a composition useful for specifically killing microbial organisms. The composition comprises a targeting moiety and an anti-microbial peptide moiety, wherein the targeting is fused in-frame with the anti-microbial peptide and specifically recognizes a target microbial organism, and wherein the composition has an anti-microbial effect on the target microbial organism.

B) The nature of the invention. As recited in paragraph 10 and 12, one aspect of the present invention provides a composition that has an antimicrobial effect on a targeted microbial organism. The targeting moiety is fused in-frame with the anti-microbial peptide moiety.

C) The state of prior art. The prior art references disclose antibody conjugates which include a therapeutic agent chemically coupled to a targeting component (See Para. 6 of the instant application, U.S.Pat. 5,057,313, U.S.Pat. 5,332,567). The drawback, however, is the non-specific linkages of the pharmaceutical agents to unknown sites on the antibody molecule (See Para. 7 of the instant application).

D) The level of one of ordinary skill. The level of one of ordinary skill in the relevant art is usually a graduate-level scientist in biology. There was a high level of skill in the art when the application was filed.

E) The level of predictability in the art. The art provides a number of examples of predictability. For example, U.S. Pat. 5,057,313 teaches conjugates of diagnostic or therapeutic agents (e.g., drugs, toxins, chelators, boron compounds and detectable labels) to an antibody and delivery of the conjugates to specific sites.

U.S.Pat. 5,332,567 (Goldenberg) also teaches antibody conjugate and methods of targeting a diagnostic or therapeutic agent to a focus of infection, wherein the antibody conjugate include an antibody specifically binding to an epitope of a pathogen and a diagnostic or therapeutic agent chemically conjugated to the antibody. Goldenberg discloses that such a conjugate can used to improve the targeting of an antibiotic or cytotoxic drug to a focus of infection so as to increase its effective concentration at the site (Col. 16, ll. 9-15).

F) The amount of direction of experimentation. The application provides ample of examples and direction for experimentation. For example, the application discloses how to select species-specific binding targeting moieties through phage display (See Example 3); how to construct a specie-specific anti-microbial composition (See Example 3 (c-1)); and how to determine the killing kinetics (Example 3(c-3)) or the killing specificity (Example 3(c-4)) of the composition.

G) The existence of working example. The instant application provides a number of examples for the targeting moiety and the anti-microbial peptides moiety. For example, the application discloses 1) targeting moieties specifically recognizing *Pseudomonas* (e.g., SEQ IDs 24-33, SEQ ID 61), 2) targeting moieties specifically recognizing *Staphylococcus* (e.g., SEQ IDs 34-51), and 3) targeting moieties specifically recognizing *E.coli* (e.g., SEQ IDs 52-60). The application also lists representative examples of anti-microbial peptide moieties (e.g., Para. 58).

One of the representative examples disclosed in the application is G10CatC wherein the SEQ ID 61 is fused in frame with novispirin G10 (an anti-microbial peptide moiety). The application demonstrates that G10CatC can specifically kills the bacterial species to which it specifically binds, but not the non-target cells (Para. 160).

H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. The application discloses step-by-step methods to generate species-specific targeting moieties, make the claimed

composition, and determine the properties of the composition. All of the methods needed to practice the invention are known to the art.

In light of the foregoing, it would not require undue experimentation to practice the claimed invention. Accordingly, Applicants respectfully request that the 112 rejections are reconsidered and withdrawn.

V. Rejections under 35 U.S.C. § 112, second paragraph

Claims 3, 24 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. In particular, the Office Action points out that the claims recite language drawn to non-elected inventions. The withdrawal of claim 3 and amendments to claim 24 and 26 make the rejections moot.

IV. Rejections under 35 U.S.C. § 102 (b) or 103(a)

Claims 1-2, 5-20 and 24-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in alternative, under 35 U.S.C. 103(a) as obvious over Goldenberg (U.S. Patent 5,332,637). According to the Office Action, Goldenberg discloses the use of an immunoconjugate to treat microbial infections wherein the immunoconjugate comprises an antibody or antibody fragment coupled to a therapeutic agent. Goldenberg further discloses that "any antibiotic or cytotoxic drug can be conjugated to the anti-pathogen antibody."

To the extent that the rejections may be applied to amended claims, Applicants respectfully traverse.

First, Goldenberg merely teaches "many drugs and toxins" or any such "antibiotic or cytotoxic drug" (See Col. 16, ll. 5-15). Although Goldenberg discloses a laundry list of "antibiotic or cytotoxic drugs," they are all chemical compounds (See Col. 16, ll. 46-54). Nowhere does Goldenberg teach or disclose a single species of "an anti-microbial peptide moiety."

A genus does not always anticipate a claim to a species within the genus. However, a reference that clearly names the claimed species anticipates the claim. MPEP 2131.02. Since Goldenberg does not clearly name the anti-microbial peptide moiety, Goldenberg does not anticipate the present claims.

Second, Goldenberg merely teaches that "antibiotic or cytotoxic drugs can be conjugated to the anti-pathogen antibody." Goldenberg discloses that "art-recognized methods of conjugating drugs or toxins to immunoglobulins are described" in a list of references (See col. 16, 32-39). However, there is no teaching that "antibiotic or cytotoxic drug" is fused in-frame with an anti-pathogen antibody. Apparently, since the "antibiotic and cytotoxic drugs" in Goldenberg are chemical compounds, these drugs cannot be fused in-frame with a targeting moiety.

In addition, the conjugating methods according to Goldenberg rely principally on chemical conjugation which suffers many drawbacks. One drawback is that the non-specific linkage of the drugs to unknown sites on the antibody molecules used for targeting may interfere with delivery of the antibody conjugate. Another is that chemical modification of a targeting antibody may substantially alter the antibody itself and thereby affect its binding to targets. (See the instant application, paragraph 7). In contrast, the claimed composition in the instant application "can be produced....without having to deal with problems associated with chemical or physical linkages." (Para. 12).

In sum, Goldenberg does not teach "an anti-microbial peptide moiety" or "fused in-frame with," therefore, Goldenberg does not anticipate the instant claims under 102(b).

By the same token, in addition to the above discussion, there is no teaching or suggestion to modify Goldenberg and reach the claimed invention. Therefore, Applicants respectfully respect that the rejections under 102(b) or 103(a) be reconsidered and withdrawn.

V. Rejections under 35 U.S.C. § 102(e)

Claims 1-2, 5, 18-20, and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Shi et al (U.S.Pat. Appl. Pub. US2004/0052814A). Applicants note that the instant application is a continuation-in-part of application No. 10/007,624, filed on Feb. 14, 2002, which is a continuation-in-part of application No. 09/910,358, filed on July 19, 2001, which is a continuation-in-part of application No. 09/378,577, filed on Aug. 20, 1999. U.S.Pat. Appl. Pub. US2004/0052814A corresponds to application No. 09/910,358, to which the instant application claims benefit under U.S.C. 120. Accordingly, Applicants respectfully request that the rejections be withdrawn.

VI. Conclusion

In view of the foregoing, the claims pending in the application are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (310) 788-3219.

Respectfully submitted,
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